

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
PRoBaND: Parkinson's Repository of Biosamples and Network Datasets

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

Yes No

2b. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

England

- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland
- Wales
- Northern Ireland
- This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes
- No

6. Do you plan to include any participants who are children?

- Yes
- No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes
- No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes
- No

9. Is the study or any part of it being undertaken as an educational project?

- Yes
- No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

NOTICE OF SUBSTANTIAL AMENDMENT

*Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.*

Details of Chief Investigator:

	Title Forename/Initials Surname
	Dr Donald Grosset
Work Address	Southern General Hospital 1345 Govan Road Glasgow
PostCode	G51 4TF
Email	donaldgrosset@gmail.com
Telephone	01412012486
Fax	01412327626

Full title of study:	PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples.
Lead sponsor:	NHS Greater Glasgow & Clyde
Name of REC:	West of Scotland REC 1
REC reference number:	11/AL/0163
Name of lead R&D office:	Research and Development Department
Date study commenced:	November 2011
Protocol reference (if applicable), current version and date:	GN11NE062 Protocol Version 1.4 4/02/2015
Amendment number and date:	1.6 25/02/2015

Type of amendment

(a) Amendment to information previously given in IRAS

Yes No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

Yes No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

The revised protocol Version 1.4 dated 19/02/2015 is enclosed. Changes are highlighted as 'tracked changes' to reflect the Sub Committee's observations made on 16 February 2015.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

The patient information sheet has been revised to incorporate the Sub Committee's comments, as has the consent form for participants for the extension phase. These are both V1.0 dated 19/02/2015. A revised GP letter for patients agreeing to participate, reflecting the changes in the PIL and Consent Form, is also attached, V1.0 dated 19/02/2015. Tracked changes versions and clean versions are attached.

Is this a modified version of an amendment previously notified and not approved?

Yes No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

This is an extension to the study, for patients with Parkinson's disease of recent onset who have reached Visit 7 (36 months), for additional visits at 42 months and 54 months.

Patients will be eligible if they have completed the previous visits and have capacity to consent to these additional visits. The Patient Information Sheet has been amended to ensure that patients will be reminded of their participation in the parent study, as per the SubCommittee's concerns. Additionally, pursuant to the SubCommittee's findings, a further amendment has been made to this document to clearly state how clinically significant findings will be managed, and advising that patients will be offered referral to the most appropriate doctor or healthcare professional.

The ICF has been amended by the addition of a section allowing patients to opt in to researchers retaining their details for future projects, as required by the SubCommittee.

The GP letter has been amended to reflect relevant changes in the other documentation.

The additional observations follow the previous pattern, meaning that there are repeat measurements made of previously recorded clinical features, and an additional blood sample, to allow measurement of progression rates and link this to their blood samples for testing for biobanking. The SubCommittee highlighted inconsistencies in PD Grading and CGI. PD grading has therefore been moved to the final visit, Visit 9 and CGI, previously performed at 6 months and 24 months, will be performed at a further 18-month interval ie 42 months, at visit 8.

The clinical domains scored remain as before, as does the blood sampling procedure.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

We have amended the PIL, ICF, and protocol in line with the SubCommittee's findings at their meeting on 16 February 2015, and have altered the GP Letter to reflect these.

List of enclosed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP letter for extension study	1.0	25/02/2015
Patient information sheet for extension study	1.0	19/02/2015
Informed consent form for extension study	1.0	19/02/2015
Protocol for study with extension, tracked changes	1.4	19/02/2015

Protocol for study with extension	1.4	19/02/2015
GP Letter for extension study, tracked changes	1.0	25/02/2015
Patient information sheet for extension study, tracked changes	1.0	19/02/2015
Informed consent form for extension study, tracked changes	1.0	19/02/2015

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Dr Donald Grosset on 25/02/2015 10:46.

Job Title/Post: Consultant Neurologist
 Organisation: NHS:Greater Glasgow & Clyde
 Email: donaldgrosset@gmail.com

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Erica Packard on 25/02/2015 11:01.

Job Title/Post: Research Co-ordinator
 Organisation: NHS Greater Glasgow and Clyde
 Email: erica.packard@ggc.scot.nhs.uk